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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,676	08/19/2003	Terry Thomas	A35897-PCT-USA-A (072667.	4695

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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,676	THOMAS ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 8, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11 and 13-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *2-4,6-11 and 13-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed February 8, 2006 has been entered.

Claims 5 and 12 are cancelled.

Claims 1-4 and 6-9 are currently amended.

Claims 1-4, 6-11 and 13-23 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 3-4, 6-11 and 13-23 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed November 4, 2006.

Applicant's arguments filed February 8, 2006 have been fully considered but they are not persuasive.

Applicants note that the claims have been amended to now specify 90% homology, or to identify specific high stringency conditions. Applicants submit that the specification provides ample support for the claims, as amended, including relevant identifying characteristics coupled to known functional characteristics, as the specification provides relevant identifying

characteristics in the form of a specific sequence (SEQ ID NO:1) and a high degree of homology to the disclosed sequence (90%). Applicants point out that the specification further discloses specific high stringency hybridization conditions to identify members of the claimed genus, and that the disclosed sequence is further described to possess promoter activity, which is a functional property associated with the identified structural characteristics. Applicants also point out that while the specification does not disclose specific sequences which are of 90% homology and hybridize under the specified stringency conditions, it would be well within the capabilities of a person of ordinary skill in the art to identify members of the claimed genus based upon the present disclosure. (reply pages 7-8)

The Examiner maintains that the claimed sequences are not described. While the specification provides relevant identifying characteristics in the form of a specific sequence (SEQ ID NO:1) that has promoter activity, the specification does not describe the features of SEQ ID NO:1 that are retained by fragments and variants of SEQ ID NO:1 that are coupled to promoter activity. Further, whether a sequence is described is not dependent on whether the specification provides an enabling disclosure. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

> The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its

> identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

In the instant case, while the specification provides a process for obtaining fragments or variants of SEQ ID NO:1, there is no further information in the specification pertaining to the relevant structural or physical characteristics of these fragments or variants; in other words, it thus does not describe fragments or variants of SEQ ID NO:1 that exhibit a specific function. Further, describing methods for preparing fragments or variants of SEQ ID NO:1 does not necessarily describe the nucleotide sequences of the fragments or variants prepared.

Claims 2-4, 6-11 and 13-23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2, does not reasonably provide enablement for other isolated nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed November 4, 2006.

Applicant's arguments filed February 8, 2006 have been fully considered but they are not persuasive.

Applicants disagree with the Examiner, and submit that it would require no more than routine experimentation to identify sequences with promoter activity. Applicants maintain that the present specification provides ample guidance for isolating nucleic acid sequences and

assaying them for promoter activity, and clearly teaches the production of constructs comprising a putative promoter and a reporter gene, and further describes a method of testing the construct for promoter activity. Applicants maintain that based upon this disclosure, it would not require undue experimentation for a person of ordinary skill in the art to determine whether a given portion of SEQ ID NO:1 exhibits promoter activity, as it is well within the abilities of a person of ordinary skill in the art to generate fragments of the sequence and to test them for promoter activity based upon the teachings of the present specification. Applicants further submit that the quantity of experimentation is reasonable in the present invention, as a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. (reply pages 8-9)

The rejection is maintained because the full scope of the claimed invention is not enabled. Applicant's arguments are inapposite to the outstanding rejection. The outstanding rejection was not predicated on a failure to provide guidance with respect to the application of general techniques such as cloning and promoter assays that are known to and within the abilities of one of ordinary skill in the art. The outstanding rejection was predicated on a failure to provide guidance with respect to the identity and location of key nucleotides and regulatory regions required for promoter function that would be retained by fragments or variants of the sequence of SEQ ID NO:1. Such guidance is necessary because it is unpredictable whether fragments or variants of the sequence of SEQ ID NO:1 would retain promoter function, because promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the promoter polynucleotide, which nucleotides and motifs may not be present in fragments or

variants of the sequence of SEQ ID NO:1. Absent such guidance one skilled in the art would have to isolate from undisclosed sources and/or synthesize numerous variant nucleic acid sequences and fragments, and then test each one for its ability to function as a promoter. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation. The undue experimentation lies not in the application of general techniques such as cloning and promoter assays, but in the selection of sequences for screening.

Allowable Subject Matter

Claim 1 is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
4/18/06